[INSERT CI TITLE/NAME]

Faculty of [INSERT/DELETE AS APPROPRIATE]

Swansea University

Singleton Park [INSERT/DELETE AS APPROPRIATE]

Swansea

SA2 8PP

Bay Campus [INSERT/DELETE AS APPROPRIATE]

Swansea

SA1 8EN

**PARTICIPANT INFORMATION SHEET**

**insert Short IRAS Study Title**

**Part A**

1. **Invitation**

Swansea University would like to invite you to take part in our research study. The research is being collected by Insert CI (and Student Name if applicable) as part of a student (delete as appropriate) research project based at Faculty XXXX, Building, Swansea University.

Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether you would like to take part and answer any questions you may have.

Please feel free to talk to others about the study if you wish. This Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part, together with more detailed information about the conduct of the study. Do ask if anything is unclear.

* 1. **Why have I been invited?**

***In this section you should insert your own text and explain briefly***

* *how potential participants have been identified and*
* *Why they have been selected.*
* *Explain specifically why the participant has been invited (e.g. because they have a specific condition, or because they are healthy individuals)*
* *State how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with x condition)*
1. **What is the purpose of the study?**
	1. **Explanation and Summary**

***Provide a brief outline of the purpose of your study in lay language****.*

1. **What will be involved?**

***This section please details***

* *What participants will experience in the research study,*
* *Please present the information in the order the participant will encounter it*
* *How will the participant be consented to and by whom i.e. researcher or clinical team member.*
* *Please specify when, where, and how many times the study activities will take place.*
	+ *For example, participants will be asked to fill in a questionnaire at the beginning of the study when attending the clinics and then one after 6 months.*
	+ *A blood sample will be collected on both occasions while at the clinic.*
* *If research is taking place in the context of clinical care, make clear which parts are research and which standard care.*

***A table or flow chart*** *can provide clarity when describing a complex series of interventions*

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***Explain to the participant***

* *How long the participant will be involved in the research.*
* *How often they will need to attend a research session; and how long visits will be.*
* *If there are multiple study visits, describe them in turn.*

***ALSO***

*If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.*

*If you will be* ***collecting samples****, give an idea of the amounts. Blood volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon.*

*If you will be using* ***tissue samples****, state whether the tissue will already be collected as part of clinical care. Biopsies may be compared to grains of rice.*

*Are you requesting use of tissue surplus to diagnostic need, or collecting additional samples?*

*If you are* ***video or voice recording****, outline the plan for transcript*

*Outline any plans for long-term follow-up.*

1. **Potential risks**

*Please list any* ***risks*** *and how they would affect the participants in this section****.***

1. **Potential benefits**

Please list any **benefits** and how they would affect the participants in this section

1. **What will happen if I don't want to carry on with the study?**

***In this section you need to make it clear that:***

* *Participation is voluntary and participants may change their minds at a later stage.*
* *Withdrawal will not affect the care they receive from any relevant service (e.g. for patients, from the NHS).*
* *What procedure is in place in case of withdrawal?*

***ALSO***

* *Are there any safety implications?*
* *Will participants be followed up and a final visit arranged?*
* *Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?*
* *If the study intends to bank tissue or data for future research, specify the effect of withdrawal on future use.*
1. **What should I consider?**

***In this section explain to the participant any***

* *Conditions which may exclude individuals from participation.*
* *Whether they can continue to take their regular medication or other prescribed or over the counter medicines.*
* *Any requirements for contraception.*
* *Whether they can participate if they are involved in other research studies*
1. **What will happen to the results of this study?**

*You should inform potential participants of your intentions with respect to publishing research findings, as well as how you intend to feedback findings to participants themselves.*

*(This might include how you are going to handle individual health related findings, as well as overall outcomes of the study).*

1. **Who is organising and funding this study?**

*Swansea University are the organisational sponsor, and the contact details are Research Governance via email* *researchgovernance@swansea.ac.uk*

*You should also tell potential participants which funder/s is/are funding your research (e.g. medical research charity, pharmaceutical company, academic institution, NHS organisation etc).*

*You should also inform the participant if the study is being conducted in collaboration with researchers from an external organization,*

1. **Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by NHS Research Ethics Committee (insert REC name) reference xxxxxxxxxxx.

1. **How have patients and the public been involved in this study? Insert/Delete as appropriate relevant sentence**
2. Service users helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study.
3. Potential participants were involved in reviewing the Participant Information Sheet.
4. In designing this study, we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out.
5. Potential participants were involved in describing the inclusion and exclusion criteria for people taking part in this study.

**Optional Sections 12-17 (insert/delete as appropriate)**

1. **Will my General Practitioner/family doctor (GP) be informed of my participation?**

***Edit if applicable***

*GPs should be notified if study participation could affect clinical care of participants.*

*GPs should be provided with a letter and the study information sheet.*

*There may also be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression*.

1. **What will happen to the Tissue samples I give?**

***Edit if applicable***

*State how the samples will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (anonymous, linked anonymous). If your study involves the analysis or use of DNA, limits on anonymity should be made clear to participants.*

 *For example: Your DNA and blood sample will be assigned a unique code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. However, your DNA is unique to you so it can never be completely anonymous.*

*You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.*

*If kept for future use, it is worth ‘future proofing’ by indicating that this research may happen*

*outside of the UK. Consider whether they may be used by commercial companies.*

*For instance: Your anonymised samples will be used mainly by local researchers (if applicable), but ethically approved research projects may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.*

1. **Will I be recorded and how will the recorded media be used?**

***Edit if applicable***

*You need to obtain the participant’s permission to record their activities on audio or video media. You must ensure that there is a clear understanding as to how these recorded media will be used. For instance, if you record a music or theatre performance, you must not publish or broadcast the recording, show it in public, or deposit it in an archive without the performers’ permission. Storage and eventual disposal of interview recordings which contain sensitive material should also be covered here.*

Example paragraph:

‘The audio and/or video recordings of your activities made during this research will be used only for analysis and for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.’

1. **What if we find something unexpected? Health related findings**

***Edit if applicable***

*Consider whether analysis of images, samples, or questionnaire responses might produce findings of clinical significance for participants or (in cases of some genetic analysis) their relatives. If so, specify the management pathway of these incidental findings. This will typically involve clinical verification and/or referral to the participant’s GP*.

1. **Participation in future research:**

***Edit if applicable***

*If you are intending to approach participants in the future, make it clear where their personal details will be kept.*

For instance:

Your contact details would be held separately from this study on [describe arrangements – e.g., a password protected computer in the Department of **XY**] and that agreeing to be contacted does not oblige them to take part in future research.

1. **Will I be reimbursed for taking part? Expenses and payments**

***Edit if applicable***

*Make clear whether they will be compensated for their time, inconvenience for having to take medications or for having to donate blood or tissue samples. It is important that potential participants understand how these payments might be influenced by their duration of involvement in your study (whether pro rata) or by factors such as the completeness of diaries they provide.*

 *Make clear whether they and/or others who might accompany them will be reimbursed for their expenses such as: travel, meals, childcare. It should not cost participants to contribute to research; at a minimum, travel should be reimbursed. This expense may sometimes be avoided by having research visits coincide with regular clinical appointments.*

**Part B** **FIXED and mandatory** INSERT/DELETE only yellow text

1. **How will we use information about you?**GDPR section HRA wording

We will need to use information from [you] [from your medical records] [your GP] [**OTHER**] for this research project. This information will include your [initials/ NHS number/ name/ contact details/ **provide a bullet list of identifiers held by site and/or sponsor for the research**].  People will use this information to do the research or to check your records to make sure that the research is being done properly.

**OPTION where applicable:** People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

**OPTION where applicable**: Some of your information will be sent to [**country X**]. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

1. **What are your choices about how your information is used?**
* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* **OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records/ your hospital/ your GP]. If you do not want this to happen, tell us and we will stop.
* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* **OPTION if data will be used for future research:** If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [**Insert details of any specific bank/ repository**]
1. **Where can you find out more about how your information is used?**

You can find out more about how we use your information.

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our leaflet available from Research Governance Swansea University
* by asking one of the research team
* by sending an email to researchgovernance@swansea.ac.uk  or Dataprotection@swansea.ac.uk
1. **Who to complain to for Data/Management/Health issues?**
* **Data issues**  GDPR IOC contact details
	+ The data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data, and can be contacted at the Vice Chancellors Office: dataprotection@swansea.ac.ukYour personal data will be processed for the purposes outlined in this information sheet
* **Health issues** Health watchdog contact details
	+ PALS or Community Health Council (specific to each trust or health board)
	+ Full Address,
	+ Postcode
	+ Tel:
	+ Email or website
* **Management issues** Head of School or Faculty contact details (specific to the Uni department)
	+ Name
	+ Email
1. **Limits to confidentiality with regards to safeguarding**

Please note that confidentiality will be maintained as far as it is possible, unless the researchers receive any information which is a cause for concern. Confidentiality may be limited or conditional as the researcher has a **duty of care** to report to the relevant authorities any possible harm/danger to the participant or others.  In such cases the University may be obliged to contact relevant statutory bodies/agencies.

1. **Further information and contact details**

If you have further questions about this study, please do not hesitate to contact us on

Contact Details:

[INSERT CI TITLE/NAME]

Faculty of [INSERT/DELETE AS APPROPRIATE]

Swansea University

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